K060093

Edwards Lifesciences
One Edwards Way • Irvine, CA USA • 92614
Phone: 949-250-2500 • Fax: 949-250-2525
www.edwards.com

5 510(k) Summary

Submitter:	Edwards Lifesciences LLC One Edwards Way Irvine, CA 92614-5686
Contact Person:	Jason Smith Project Manager, Regulatory Affairs
Date Prepared:	January 10, 2006
Trade name:	PreSep Oligon Oximetry Catheters
Classification Name:	Catheter, Oximeter, Fiberoptic (21 CFR 870.1230)
Predicate Devices:	Central Venous Oximetry Probe Catheter and Probe, Vantex Central Venous Catheters with Oligon material, Edslab Dual Lumen Regional Saturation Oximetry Catheter
Device Description:	The PreSep Oligon Oximetry Catheters are used with Edwards oximetry monitors to continuously measure oxygen saturation. These catheters also provide the means for infusion of solutions, measuring pressure and taking blood samples.
Intended Use:	The PreSep Oligon Oximetry Catheters are intended to provide the means for infusion of solutions, measuring pressure and taking blood samples through the distal, proximal and medial lumens. The PreSep Oligon Oximetry Catheters also provide the means for continuously monitoring oxygen saturation using an Edwards Lifesciences oximetry monitor.
Comparative Analysis:	The PreSep Oligon Oximetry Catheters have been demonstrated to be as safe and effective as the predicate devices for their intended use.
Functional/Safety Testing:	The PreSep Oligon Oximetry Catheters have successfully undergone functional testing. These products have been shown to be equivalent to the predicate devices.
Conclusion:	The PreSep Oligon Oximetry Catheters are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 28 2006

Edwars Lifesciences LLC
c/o Mr. Jason Smith
Project Manager, Regulatory Affairs
One Edwards Way
Irvine, CA 92614-5686

Re: K060093
Trade Name: PreSep Oligon Oximetry Catheters
Regulation Number: 21 CFR 870.1230
Regulation Name: Fiberoptic Oximeter Catheter
Regulatory Class: Class II (two)
Product Code: DQE
Dated: March 29, 2006
Received: March 31, 2006

Dear Mr. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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4 Indications for Use Statement

510(k) Number (if known): K060093

Device Name: PreSep Oligon Oximetry Catheters

Indications for Use:

The PreSep Oligon Oximetry Catheters are indicated for hemodynamic monitoring through blood sampling, pressure monitoring and oxygen saturation measurements.

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vachney

(Division Sign-Off)
Division of Cardiovascular Devices

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